

### **REMARKS**

This is in response to the Office Action mailed January 3, 2007.

Claims 1, 5, 8, 9 and 10 have been amended. New claims 11-18 have been added. Support for amendments to the claims can be found throughout the originally filed application, e.g., paragraphs 36, 55 and 79. No new matter is introduced.

Independent claim 1 and its dependent claims 2-7 and 11-14 and independent claim 8 and its dependent claims 9-10 and 15-18 are currently pending and at issue.

### **Claim Rejections - 35 U.S.C. §112**

The Examiner has rejected claims 1-10 under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner asserts that in claims 1 and 8, the phrase "during a period of time" is vague because the period is unlimited rendering the metes and bounds of the claim unclear. Applicants disagree. The limit to the period is defined in claim 1, e.g., the period is the time it takes to "produc[e] a benefit attributable to the dairy products selected from the group consisting of inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the overweight animal." Also, the "period of time" is defined, for example, as at least six weeks, e.g., paragraphs 55 and 79. New dependent claims 11 and 15 have been added to recite that the period of time comprises at least about six weeks.

The Examiner also asserts that in claims 1 and 8, the phrase "above suboptimal levels" is vague because it is subjective as to what is suboptimal. Applicants disagree. The suboptimal amount is defined throughout the specification, for example, 0.4% calcium, e.g., paragraphs 55 and 79. However, to expedite prosecution of the application, the claims have been amended to replace the term "above suboptimal levels" with "at least about 0.4%. Also, new claims 12 and 16 and 13 and 17 have been added to recite that the therapeutically effective amount is at least about 1.2% calcium or 2.4% calcium, respectively.

In addition, the Examiner asserts that in claims 1 and 8, the phrase "below ad lib" is vague because it is unclear as to how "ad lib" is determined. Applicants disagree. This term is clear and can be determined, as set forth in the claims and specification, and as would be understood by one skilled in the art, or even layman, e.g., an individual who is feeding a pet or farm animal.

Ad lib is defined as "without restraint or limit" (Merriam-Webster Online Dictionary <<http://www.m-w.com/cgi-bin/dictionary>> visited March 10, 2006). It is commonly understood that there are two practices of energy intake, e.g., food, drinks or calories, either (1) ad lib or (2) restricted. Ad lib is a commonly used term that is understood to be the unrestricted intake of food or calories. Restricted diets may include a variety of diets, including for example, restricting caloric intake. As is readily apparent from the specification, the restriction of unmodified or ad lib caloric intake may be slight or more extensive, for example by 70%, e.g., paragraph 79.

An individual, e.g., one feeding the pet or farm animal, practicing the invention can readily determine limiting their pet or farm animal's unrestricted eating. New dependent claims 14 and 18 have been added to recite that the caloric intake is restricted by 70%.

The Examiner also contends that in claims 1 and 10, the term "farm animal" is vague because it can include invertebrates such as insects and worms; in claim 8, the phrase "animal food" is vague because the term includes human food and in claim 9, the phrase "pet food" is vague because it can include invertebrates. These claims have been amended to recite a mammalian farm animal, a non-human animal food and a mammalian pet food. These amendments are supported in the originally filed application, e.g., paragraph 36.

Applicants contend that the above-referenced clarification and amendments to the claims should obviate the Examiner's 112 rejections and respectfully request they be withdrawn.

### **Claim Rejections - 35 U.S.C. §103**

The Examiner has rejected claims 1-7 under U.S.C. § 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988). Applicants respectfully traverse.

The Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143. Metz does not teach or expressly or impliedly suggest all of the limitations set forth in the present claims. There is no motivation to combine the reference with other knowledge and there would not be a reasonable expectation of success.

The claimed invention is distinct from Metz, which does not disclose, teach or suggest the combination of elements set forth in independent claim 1. Nowhere in Metz is a method disclosed comprising administering on a daily basis one or more servings of dairy products to the animal in an amount sufficient to induce weight loss, reduce weight gain, and/or increase the

metabolic consumption of adipose tissue in the non-human animal, wherein the one or more servings comprises a therapeutically effective amount of calcium, and maintaining the overweight animal on a restricted caloric diet below ad lib.

Instead, Metz is directed to using the simultaneous administration of a combination of calcium and sodium. Metz' hypothesis and results suggest that calcium alone is insufficient to reduce body weight, and that high sodium is required with calcium.

It would not have been obvious in view of Metz to use dairy products to induce weight loss as set forth in the present invention because of its unobvious and unexpected results. The studies of animals reported in the application demonstrate the benefit of high dairy and high calcium animal diets for weight loss. As is universally recognized, dairy's natural role is food for young mammals gaining weight. The benefits of dairy to induce weight loss were not previously known and conflicted with the conventional view of dairy as a weight gain food. Further, dairy products were generally discouraged for most diets due to concerns regarding fat content.

Therefore, Metz, either alone or in combination with other knowledge, does not disclose, teach or suggest the claimed invention as set forth in claim 1 or its dependent claims 2-7 and 11-14, which include additional limitations distinguishing them from the cited references.

Claims 1-7 and 11-14 are patentable over Metz because it does not disclose, teach or suggest the present invention. This rejection is traversed. The Applicants respectfully request that this rejection be withdrawn.

### **Claim Rejections - 35 U.S.C. §102**

The Examiner has rejected claims 8-10 under U.S.C. § 102(b) as being unpatentable over Schroeder et al (U.S. Patent No. 4,027,043). The Examiner asserts that Schroeder teaches a solid animal feed supplement containing calcium, which is poured into packages. The Examiner contends that ruminants are disclosed and as to the claimed pet food, such is allegedly merely an intended use. The Examiner further renders an obviousness rejection that as to the accompanying description of a method of use, such instructions are obvious in view of Metz, therefore do not render the composition patentable.

Applicants traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. In order to anticipate, the elements of the prior art must be present and arranged as required by the claim. § 2131.

Here, the Examiner admits that Schroeder does not recite all of the elements of the present claims, and applies Schroeder in light of Metz. Applicants contend that the application of Schroeder under 102(b) is incorrect and should be withdrawn.

The Examiner is correct that Schroeder does not teach all the claimed elements. For example, Schroeder does not teach an animal food package comprising a container, a calcium-fortified or dairy-containing animal food within the container, a description indicating that consuming the animal food according to the dietary plan during the period of time produces benefits attributed to calcium in inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue, in the overweight animal.

Furthermore, Schroeder does not teach or suggest a dietary plan comprising, in combination during a period of time: (a) administering on a daily basis one or more servings of the food, the one or more servings comprising a therapeutically effective amount of above at least 0.4 % calcium, and (b) restricting caloric intake below ad lib.

Moreover, as discussed above, Metz does not teach or suggest all the elements of the claimed invention, nor does it cure the defects of Schroeder.

The combination of elements of the present claims are not taught, disclosed or suggested in Metz or Schroeder, alone or in combination.

The Applicants have previously argued that Schroeder teaches away from the present invention because it teaches the use of molasses and/or fat to supply the energy for maintenance and weight gain of the animals (abstract). The Examiner disputes this contention, asserting that weight maintenance or gain is due to the molasses and/or fat in the composition, and concludes that the present claims do not exclude these ingredients.

Applicants disagree. The present invention includes a dietary plan comprising restricting caloric intake. Molasses and fat are high in calories and therefore are excluded by the present claims.

Therefore, Schroeder, either alone or in combination Metz, does not disclose, teach or suggest the claimed invention as set forth in claim 8 or its dependent claims 9-10 and 15-18. Applicants respectfully request that this rejection be withdrawn.

**Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-18 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment to deposit account no. 22-0261.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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